

REMARKS

Reconsideration and allowance of the above-referenced application are respectfully requested. Applicant petitions for a two-month extension of time to reply to the office action.

Applicant thanks Examiner Bachman for the courtesy extended in the interview with applicant's attorney, Fred Hernandez, and Natalie Schiller on May 20, 2009 at 2PM. A summary of the topics discussed in the interview is included in the following remarks.

Rejections under 35 U.S.C. §103 in view of Maisano and Aldrich

Claims 1-3, 5-9, 21, 23, 25, and 26 stand rejected as allegedly being obvious over European Journal of Cardio-thoracic Surgery 13 (1988) 240-246 ("Maisano") in view of U.S. Patent No. 6,355,030 ("Aldrich"). Claims 4, 10, and 24 were rejected as allegedly being obvious over Maisano and Aldrich further in view of Carpentier. Applicants respectfully traverse the rejection as Maisano and Aldrich, both alone and in combination, fail to teach or suggest each and every element of the claims.

Claim 1

As discussed in the interview, Maisano fails to disclose or suggest, *inter alia*, using a first catheter to deploy a first structure from the catheter directly on an annulus of the heart valve, using graspers on the first catheter to grasp the leaflets of the heart valve, and further using the first catheter to attach a staple directly on the leaflets. Instead, Maisano discloses the use of first and second catheters in two separate procedures. Maisano discloses performing a double orifice repair in a redo procedure on a patient that had previously received a Carpentier annuloplasty procedure. ("A double orifice repair was carried out in the redo patient ... after previous Carpentier annuloplasty. In this case, the procedure was successfully carried out leaving the previously implanted ring in site." Maisano, page 242.) Because the double orifice repair in Maisano is performed in a subsequent, separate procedure to the annuloplasty, it would be highly unlikely, if not impossible, to perform both the double orifice repair and the annuloplasty using the same, first catheter. Moreover, Maisano makes no mention whatsoever of attaching a staple directly on the leaflets.

The examiner asserted on page 2 of the office action that certain elements of the claims would not be given patentable weight in view of the *Ex Parte Pfeiffer* case. In the interview, the examiner acknowledged that *Ex Parte Pfeiffer* is not applicable to the pending claims and withdrew her remarks regarding *Ex Parte Pfeiffer* contained in the office action.

Aldrich also fails to disclose or suggest using a first catheter to deploy a first structure from the catheter directly on an annulus of the heart valve and further using the first catheter to attach a staple directly on the leaflets. Aldrich merely relates to a thermal heating member that supplies thermal energy to a heart valve. Aldrich makes no mention whatsoever of deploying a second structure directly on the leaflets from the same catheter that deployed a first structure directly on the annulus.

In view of the foregoing, Applicants request reconsideration and withdrawal of the rejection of claim 1 in view of Maisano and Aldrich. Claims 2, 3, and 5 all depend from claim 1 and are patentable over the prior art for at least those reasons articulated with respect to claim 1. The dependent claims are also patentable on their own merit as the claims recite features that are not disclosed or suggested by Maisano or Aldrich. Claims 4 and 10 were rejected as being unpatentable over Maisano in view of Aldrich and further in view of U.S. Patent No. 5,593,435 to Carpentier. Claims 4 and 10 both depend from claim 1 and are patentable over the prior art for at least those reasons articulated with respect to claim 1 as well as on their own merit.

Claim 11

Maisano fails to disclose or suggest, *inter alia*, using a first catheter to implant an annuloplasty device from the first catheter directly on an annulus of the heart valve, using the first catheter to grasp the leaflets of the heart valve, and further using the first catheter to attach a structure directly to a first valve leaflet and a second valve leaflet of the heart valve. As discussed above, Maisano discloses performing a first annuloplasty procedure on a patient and subsequently performing a double orifice repair in a separate procedure. Maisano makes no mention of performing both the annuloplasty and the double orifice repair using only a first catheter. Aldrich fails to provide the missing teaching.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 11 in view of Maisano and Aldrich.

Claim 21

Maisano fails to disclose or suggest, *inter alia*, using a first catheter to implant an annuloplasty device from the catheter directly on an annulus of the heart valve, using the first catheter to grasp the leaflets of the heart valve; and further using the first catheter to coapt leaflets of the heart valve. As discussed above with reference to claim 1, Maisano discloses using two separate procedures, which necessitates the use of first and second, separate catheters. Aldrich fails to provide the missing teaching.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 21 in view of Maisano and Aldrich. Claims 23, 25, and 26 all depend from claim 21 and are patentable over the prior art for at least those reasons articulated with respect to claim 21. The dependent claims are also patentable on their own merit as the claims recite features that are not disclosed or suggested by Maisano or Aldrich.

Rejections under 35 U.S.C. §103 in view of Noera and Aldrich

Claims 1-3, 5-9, 11-17, 19, 21, 23, 25, and 26 stand rejected as allegedly being obvious over Annals of Thoracic Surgery (“Noera”) in view of Aldrich. Claims 4, 10, 28 and 24 were rejected as allegedly being obvious over Noera and Aldrich further in view of Carpentier. Applicants respectfully traverse the rejection as Noera and Aldrich, both alone and in combination, fail to teach or suggest each and every element of the claims. Claims 27-29 and 31-35 were rejected as allegedly being obvious over Noera in view of Aldrich and Carpentier.

Claim 1

Noera fails to disclose or suggest, *inter alia*, using graspers on the first catheter to grasp the leaflets of the heart valve and further using the first catheter to attach a staple directly on the leaflets, wherein the staple attaches opposed points on the valve leaflets of the heart valve together. Noera makes no mention whatsoever of using a catheter to grasp leaflets of the heart valve. Noera also does not make any mention of attaching a staple directly on the leaflets, wherein the staple attaches opposed points on the valve leaflets of the heart valve together. The examiner asserted that Noera discloses applying a suture to adjacent leaflets. However, the suture is not a staple and it is not used to attach opposed points on the valve leaflets of the heart

valve together. Rather, Noera teaches that the suture is used to stitch a detached leaflet to the annulus. Aldrich fails to provide the missing teaching.

In view of the foregoing, Applicants request reconsideration and withdrawal of the rejection of claim 1 in view of Noera and Aldrich. Claims 2, 3, and 5 all depend from claim 1 and are patentable over the prior art for at least those reasons articulated with respect to claim 1. The dependent claims are also patentable on their own merit as the claims recite features that are not disclosed or suggested by Noera or Aldrich. Claims 4 and 10 were rejected as being unpatentable over Noera in view of Aldrich and further in view of Carpentier. Claims 4 and 10 both depend from claim 1 and are patentable over the prior art for at least those reasons articulated with respect to claim 1 as well as on their own merit.

Claim 11

Noera fails to disclose or suggest, *inter alia*, using the first catheter to grasp the leaflets of the heart valve, and further using the first catheter to attach a structure directly to a first valve leaflet and a second valve leaflet of the heart valve. As discussed, Noera makes no mention of grasping the leaflets and further makes no mention of attaching a structure directly to the first and second valve leaflets. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 11 in view of Noera and Aldrich. Claims 12-17, 19, and 21 all depend from claim 11 and are patentable over the prior art for at least those reasons articulated with respect to claim 11. The dependent claims are also patentable on their own merit as the claims recite features that are not disclosed or suggested by Noera or Aldrich. Claims 18 and 20 were rejected as being unpatentable over Noera in view of Aldrich and further in view of Carpentier. Claims 18 and 20 both depend from claim 11 and are patentable over the prior art for at least those reasons articulated with respect to claim 11 as well as on their own merit.

Claim 21

Noera fails to disclose or suggest, *inter alia*, using a first catheter to grasp the leaflets of the heart valve and further using the first catheter to coapt leaflets of the heart valve by attaching a structure from the first catheter directly to the leaflets so as to reduce regurgitation in the heart valve. As discussed, Noera makes no mention of grasping the leaflets and further makes no

mention of attaching a structure from the first catheter directly to the leaflets. Aldrich fails to provide the missing teaching.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 21 in view of Noera and Aldrich. Claims 23, 25, and 26 all depend from claim 21 and are patentable over the prior art for at least those reasons articulated with respect to claim 21. The dependent claims are also patentable on their own merit as the claims recite features that are not disclosed or suggested by Noera or Aldrich. Claim 24 was rejected as being unpatentable over Noera in view of Aldrich and further in view of Carpentier. Claim 24 depends from claim 21 and are patentable over the prior art for at least those reasons articulated with respect to claim 21 as well as on its own merit.

Claim 27

Claims 27-29 and 31-35 stand rejected as allegedly being obvious over Noera in view of Aldrich and further in view of Carpentier. None of Noera, Aldrich or Carpentier disclose or suggest implanting the annuloplasty device on the annulus of the heart valve so that the entire annuloplasty device is positioned entirely on an atrial side of the annulus of the heart valve. The examiner asserted that Carpentier at column 4, lines 43-55 and Figure 4 show an annuloplasty ring on the atrial side of the annulus. However, neither the cited section of Carpentier or Figure 4 disclose that the annuloplasty ring is on the atrial side of the annulus.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 27. Claims 28-29 and 31-35 all depend from claim 27 and are patentable over the prior art for at least those reasons articulated with respect to claim 27. The dependent claims are also patentable on their own merit as the claims recite features that are not disclosed or suggested by the cited art.

Conclusion

The above is believed to be a complete response. In view of the amendments and remarks herein, Applicants believe that all claims are now in condition for allowance and ask that these pending claims be allowed. The foregoing comments made with respect to the positions taken by the Examiner are not to be construed as acquiescence with other positions of the Examiner.

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Serial No. : 10/820,581
Filed : April 7, 2004
Page : 13 of 13

Attorney's Docket No.: 37531-501C02US

that have not been explicitly contested. Accordingly, the arguments for patentability of a claim should not be construed as implying that there are not other valid reasons for patentability of that claim or other claims. The Examiner is invited to telephone the undersigned to resolve any remaining issues and/or informalities and expedite prosecution of this case.

Authorization for a credit card payment of the filing fee of \$245 is submitted herewith. No additional fees are believed to be due, however, the Commissioner is authorized to charge any additional fees or credit overpayments to Deposit Account No. 50-0311.

Respectfully submitted,



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Date: June 29, 2009

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